UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THOMAS M. BEHR and
DAVID M. GOLDENBERG

Appeal No. 2006-2417
Application No. 09/200,791

ON BRIEF

Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-9, 11-21, 23-29, and 31-41, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A method of reducing kidney retention of a protein conjugate in a patient, comprising administering to said patient one or more compounds selected from the group consisting of D-lysine, poly-lysine having a molecular weight in the range 1-60 kD, pharmaceutically acceptable salts thereof and carboxyl derivatives thereof, wherein said protein conjugate has a molecular weight that is not greater than about 60 kD
wherein the pharmaceutically acceptable salt and carboxyl derivative of polylysine has a molecular weight in the range 1-60 kD,
whereby said compound or compounds reduce kidney retention of said conjugates.

The references relied upon by the examiner are:

Grey et al. (Grey)	5,380,513	Jan. 10, 1995
Raines et al. (Raines)	5,840,296	Nov. 24, 1998 (filed Oct. 15, 1997)

Behr et al. (Behr), "Reduction of the Renal Uptake of Radiolabeled Monoclonal Antibody Fragments by Cationic Amino Acids and Their Derivatives," Cancer Research, Vol. 55, pp. 3825-3834 (1995)

GROUNDS OF REJECTION

Claims 1-8, 11-19, 23-28, 31-39, and 41 stand rejected under 35 U.S.C. § 102(b) as anticipated by Behr.

Claims 1-9, 11-21, 23-29, and 31-41 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Behr, Grey, and Raines.

We affirm.

CLAIM GROUPING

Appellants do not separately group or argue the claims on appeal. Accordingly, the claims will stand or fall together. Since all claims stand or fall together, we limit our discussion to representative independent claim 1. Therefore with regard to the anticipation rejection, claims 2-8, 11-19, 23-28, 31-39, and 41 will stand or fall together with claim 1. With regard to the obviousness rejection, claims 2-9, 11-21, 23-29, and 31-41 will stand or fall together with claim 1. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

DISCUSSION

The application before us on appeal is a continuation-in-part of Application No. 08/407,899 which has a filing date of March 21, 1995, and issued on December 1, 1998 as United Stated Patent No. 5,843,894 ('894). As the examiner explains (Answer, page 9), the subject matter disclosed and claimed in the '894 patent is limited to a method of reducing kidney retention of antibody and antibody fragments. See e.g., '894, claim 1. In contrast, claim 1 before us on appeal is directed to a method of reducing kidney retention of a protein conjugate. According to the examiner (id.), the antibody or antibody fragment conjugates disclosed in the '894 patent are species of the protein conjugate genus set forth in claim 1 of the instant application. In this regard, the examiner asserts (Answer, bridging sentence, pages 8-9), the species of the '894 patent are insufficient to support the protein conjugate genus now on appeal. Therefore, the examiner denied appellants' claim of priority to the '894 patent. Having denied appellants priority claim, the examiner applied the Behr and Raines references which are available as prior art between the November 30, 1998 filing date of the instant application and the '894.[1]

The rejections of record involve the Behr reference, which published September 1, 1995 (see Brief, page 5). Therefore, Behr is available as prior art under 35 U.S.C. § 102(b). It is undisputed on this record that Behr teaches a species within the scope of claim 1 before us on appeal. See e.g. Answer,

[1] Grey, the only other reference relied upon, issued prior to the effective filing date of appellants '894 patent.

page 4. It is axiomatic that the disclosure of a species in a reference is sufficient to prevent a later applicant from obtaining generic claims. In re Gosteli, 872 F.2d 1008, 1010, 10 USPQ2d 1614, 1616 Fed.Cir.1989) (holding that earlier species invention anticipates later generic claim). Therefore, it would seem clear that rejections of record turn on our findings as to whether appellants are entitled to benefit from their claim of priority to the '894 patent. As appellants explain it (Reply Brief, page 2),

> [a]ppellants and the [e]xaminer are in agreement that a major issue in this Appeal is whether or not the instant claims are entitled to the March 21, 1995 priority date of . . . [the '894 patent]. A central issue of contention between the [e]xaminer and [a]ppellants is whether or not there is sufficient written description support in the . . . ['894 patent] to justify a March 21, 1995 priority date for the instant claims.

Accordingly, as we understand the record, the examiner and appellants agree that the only way appellants can overcome the examiner's rejections under 35 U.S.C. § 102(b) and § 103 is to remove Behr as prior art. On this record, the only way appellants can remove the Behr reference is by obtaining the benefit of the filing date of the '894 patent. Accordingly, the dispositive issue before us is one of priority.

Priority:

We begin by noting that claims found in a later-filed application are entitled to the filing date of an earlier application if, inter alia, the disclosure in the earlier application provides an adequate written description of the later-filed claims under 35 U.S.C. § 112, first paragraph. See Tronzo v. Biomet, Inc.,

156 F.3d 1154, 1158, 47 USPQ2d 1829, 1832 (Fed. Cir. 1998) (discussing requirements of claiming benefit of priority date of earlier application under 35 U.S.C. § 120).

As appellants point out (Brief, page 6), this requires the disclosure in the earlier application to reasonably convey to one of ordinary skill in the art that the inventors possessed the later-claimed subject matter when they filed the earlier application. See e.g., Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479, 45 USPQ2d 1498, 1502-1503 (Fed. Cir. 1998); Univ. of Cal. v. Eli Lilly and Co., 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997)[2]. Upon consideration of the '894 patent, we find that '894 discloses (column 1, lines 4-7), "[t]his invention relates to a method for reducing renal uptake of monoclonal antibody fragments used for radioimmunodiagnosis (RAID), immunotherapy, and radioimmunotherapy (RAIT)." '894 further discloses (column 1, lines 16-18), "[a] major drawback to the use of radiolabeled antibody fragments for imaging and therapy is the relatively high uptake and retention of radioactivity in the kidney." We note that this section of the '894 patent does not speak to proteins generally, but instead is very specifically drawn to radiolabeled antibody fragments.

Regarding proteins generally, appellants point out (Brief, page 7) that the '894 patent discusses proteins is at column 1, lines 33-50. While it is true that the '894 patent briefly discusses proteins as part of the background section of the '894 disclosure, the '894 patent discloses

[2] We recognize that appellants' Reply Brief makes reference to these cases as well. Reply Brief, pages 3-4.

(column 1, lines 39-63) that current methodology for decreasing kidney uptake of radiolabeled peptides requires either "continuous infusion" or "repeated injection," both of which "cause substantial inconvenience and increased costs in a clinical setting. In addition, the most clinically efficacious dosages of amino acids approach the maximum levels that can be physiologically tolerated before toxicity is observed." Therefore, the '894 patent discloses (column 1, lines 65-67, emphasis added), "[i]t is therefore an object of the present invention to provide methods that greatly reduce kidney uptake of antibody fragment conjugates." The remainder of the patent discusses antibody fragment conjugates. We find no disclosure in the '894 patent that would suggest that its methodology would be useful for all protein conjugates as is now claimed. For their part, other than citing the first column of the '894 patent, appellants fail to direct our attention to any other portion of the '894 patent that would suggest or describe the applicability of the disclosed methodology for non-antibody conjugates.

We also recognize appellants' argument (Brief, page 3) that the facts in this case are different than those in Lilly. According to appellants (Reply Brief, page 3), "[i]n the present case, no nucleic acid or protein sequences are part of the claimed subject matter. Rather, the claims recite protein conjugates of 'not greater than about 60 kD.' This is a simple physical property of the protein conjugate, that is not dependent upon the amino acid sequence of the protein or encoding nucleic acids." Accordingly, appellants assert (id.), cases such as Lilly and Amgen Inc. v. Chugai Pharmaceutical Co., Ltd. 927 F.2d 1200, 18 USPQ2d

1016 (Fed. Cir. 1991) "are not valid precedent for the written description question addressed herein." We disagree.

While the subject matter in Lilly was directed to genetic material, the requirements of the statute applies to all types of invention. See Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 925, 69 USPQ2d 1886, 1893 (Fed. Cir. 2004) ("Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.")

Whether or not an application adequately describes a claimed invention is determined as of the application's filing date. See Hyatt v. Boone, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998) ("[T]he purpose of the description requirement is 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.'") For the reasons set forth above, we find that the facts on this record weigh in favor of the examiner – the antibody species disclosed in the '894 patent do not support the broader genus of any protein conjugate. As discussed above, there is simply no disclosure in the '894 patent to suggest the applicability of the disclosed methodology to anything other than antibody conjugates or for use in any other application other than radioimmuno-therapy or diagnostics. See e.g., the '894 patent, column 2, lines 1-17, where the patent discloses "[i]n accomplishing, the foregoing object of the invention, there has been provided . . .

a method of reducing kidney uptake of antibody fragment conjugates in a patient during radioimmunodiagnosis or immunotherapy. . . ." There is no disclosure in the '894 patent that the disclosed methodology would be generally applicable to any protein conjugate.

For the foregoing reasons, it is our opinion that the '894 patent does not provide a description of the genus of protein conjugates set forth in the claims now before us on appeal. Accordingly, it is our opinion that the claims before us on appeal do not receive the benefit of the filing date of the '894 patent.

Anticipation:

For the foregoing reasons, we find no error in the rejection of claim 1 under 35 U.S.C. § 102(b) as anticipated by Behr. Therefore, the rejection is affirmed. As set forth above claims 2-8, 11-19, 23-28, 31-39, and 41 fall together with claim 1.

Obviousness:

Having found claim 1 anticipated by Behr, we find no error in the obviousness rejection of claim 1, for obviousness is the epitome of anticipation. Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716, 223 USPQ 1264, 1271 (Fed. Cir. 1984) ("a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for 'anticipation is the epitome of obviousness,' In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982).").

Therefore, the rejection is affirmed. As set forth above claims 2-9, 11-21, 23-29, and 31-41 fall together with claim 1.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner)
Administrative Patent Judge)
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) BOARD OF PATENT
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Donald E. Adams) APPEALS AND
Administrative Patent Judge)
) INTERFERENCES
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Lora M. Green)
Administrative Patent Judge)

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